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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/361,542	07/27/1999	DOUGLAS JOSEPH DOBROZSI	7247M	5652
27752	7590	10/31/2003	EXAMINER	
			PULLIAM, AMY E	
		ART UNIT		PAPER NUMBER
		1615		25
DATE MAILED: 10/31/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/361,542	DOBROZSI, DOUGLAS JOSEPH	
	Examiner	Art Unit	
	Amy E Pulliam	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 27 August 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 36,38,39,41-46 and 48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 36,38,39,41-46 and 48 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Request for Extension of Time, and the Amendment G, both received August 27, 2003.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. The examiner recognizes that the rejection set forth is similar to the rejection set forth previously, in paper number 15. However, the examiner reasserts this rejection for two reasons. First, this rejection has never been presented with respect to the presently pending claims. The claims pending at the time paper 15 was issued were directed to a method of providing a mucoadhesive coating to mucosa of the esophagus. However, the claims pending now are drawn to a composition and a method of administering an active agent. Second, upon careful examination and reconsideration, it is the position of the examiner that this rejection is appropriate over the instant claims. Therefore, please see the following rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 36, 38, 39, 41-46, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over the product *Silicol*, which is manufactured by Saguna GmbH in Germany, in view of WO 98/48814 to Banning *et al.*.

Silicol is a unique gel composition which consists of water and colloidal silicic acid. The advertisement relied upon for this rejection states that when *Silicol* is taken three times a day with meals, it forms a soothing coating over the lining of the stomach and intestines. Further, it teaches that *Silicol* coats and protects the lining of the gut.

The advertisement for *Silicol* does not teach that active ingredients be present in the formulation. However, it is the position of the examiner that the method as claimed is to use colloidal silica to coat the mucosal of the gastrointestinal tract. Furthermore, it is also the position of the examiner that the addition of an active agent does not affect the mucoadhesiveness of the composition. Lastly, as stated by applicant in their specification, all prior art mucoadhesive systems require polymers for the mucoadhesive properties. However, as shown by *Silicol*, it has been discovered that colloidal silicic acid has these mucoadhesive properties.

Additionally, the purpose of *Silicol* is to coat the gastrointestinal tract. The reference further teaches that this composition is useful for persons suffering from gastritis, flatulence, heartburn, nausea and diarrhea. The reason it is useful is because it coats the gastrointestinal tract, therefore absorbing toxins and irritants, and protecting the lining of the gut. It is the position of the examiner that this protection is meant to protect the gut from irritating active agents as well. Therefore, it would be obvious to include active agents in the present composition, as the composition would protect the gut from the active, and allow comfortable treatment.

The Banning *et al.* reference is relied upon for the teaching that substances which are known to coat the gastrointestinal mucosa are known in combination with active agents. More specifically, Banning *et al.* teach that a well known approach to treating oesophageal and gastric disorders is to use a material which provides a protective coating on the mucus or mucosa of the gastrointestinal tract (p 5, l 1-4). Furthermore, Banning *et al.* teach that the agent which forms the protective coating can be combined with an active agent (p 12, l 10-14).

Although the Banning *et al.* reference relies on alginate to form the protective coating, rather than silica, this is not the reason the reference is relied upon. This reference is relied upon for the teaching that it is known in the art to coat the gastrointestinal tract in order to treat gastric disorders. Additionally, it is known to administer the mucoadhesive protective materials in combination with active agents. The advertisement for *Silicol* shows that a new material has been found which is successful in coating the gastrointestinal tract in order to protect it and treat gastric disorders.

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Furthermore, *Silicol* is taught to provide rapid relief for people with inflammatory conditions of the intestine. As discussed above, Banning *et al.* teach a composition for this same purpose. As stated in *In Re Kerkhoven*, 205 USPQ 1069, 1072 (CCPA- 1980), "It is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose." As this court explained in Crockett, 126 USPQ 186, 188 (CCPA- 1960), the idea of combining them flows logically from their having been individually taught in the prior art.

One of ordinary skill in the art would be motivated to use this new mucoadhesive material in the same manner the previously known mucoadhesive material were used, which includes in combination with active agents. The expected result would be a mucoadhesive formulation, useful in administering active agents, useful in protecting the lining of the gut, and successful in treating a variety of gastric disorders. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Correspondence

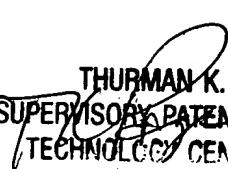
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A. Pulliam
Patent Examiner
Art Unit 1615
October 28, 2003 4


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600